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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,889	11/14/2003	Benjamin Levinson	WELLSP 3.0-003	1106

25226	7590	09/10/2007
MORRISON & FOERSTER LLP		
755 PAGE MILL RD		
PALO ALTO, CA 94304-1018		

EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/713,889

Applicant(s)

LEVINSON ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5,8-31 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5,8-31 and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/8/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 6/7/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1, 6-7, and 32-33 have been canceled.
2. Claims 21, 23 and 29 have been amended.
3. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 2-5, 8-31 and 34-37 are pending in the case.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 21, 23-28 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The rejection of Claim 29 under 35 U.S.C. 102(b) as being anticipated by Goel et al (WO 97/05152; document cited in IDS of 10/3/2006) has been overcome by amendment.

Amended claim 29 is drawn to a Tin mesoporphyrin composition, The prior art teaches Cobalt mesoporphyrins.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 2-5, 8-10, 22, 29-30 and 34-37 under 35 U.S.C. 103(a) as being unpatentable over Robinson (US Patent Pub. No. 2003/0100752) in combination with Drummond (Annals of New York Academy of Sciences, 1987, 514, 87-95) and Bettelheim et al (General, Organic and Biochemistry, 1998, page 596) and the rejection of Claims 11-20 under 35 U.S.C. 103(a) as being unpatentable over Niedballa et al (US 5,275,801) are both being maintained for reasons of record.

Regarding claims 2-5, 8-10, 22, 29-30 and 34-37 applicants argue that:

1. Robinson lists over 100 categories of substituents that can be chosen for each of the twelve substituents R1 through R12, which reads on millions of compounds and cannot read on tin mesoporphyrins complexed to amino acids. Robinson also lists fifteen metals.

2. The secondary reference by Drummond does not mention mesoporphyrin or amino acids Even though Drummond mentions tin protoporphyrin was the most potent compound in

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vitro, the most potent compound in vivo was chromium protoporphyrin. Hence Drummond does not cure the deficiency of Robinson.

3. Niedballa does not even teach mesoporphyrin and thus does not disclose all of the elements of the instant claims.

This is not found to be persuasive.

Robinson teaches that one of the preferred metal ions complexed to the core is Tin (page 32, paragraph 183; page 45 claim 1) and the compounds of Robinson are complexed to amino acids. Robinson, at paragraph 211 states that exemplary compounds include solutions of the new compounds in solvents, most preferably water. This means that the compounds are water soluble. Robinson additionally states at paragraph 208 that solutions of the compounds can be made in water suitably mixed with a surfactant. Robinsons application may be different but his teaching shows that these compounds are water soluble including the tin porphyrins as instantly claimed.

Drummond, drawn to metalloporphyrins, teaches control of heme metabolism using tin-protoporphyrins (page 87, introduction, last paragraph). Tin protoporphyrin was by far the most potent (page 88, Results and Discussion; page 89). Tin protoporphyrin is structurally similar to tin-mesoporphyrin except that the protoporphyrin has an ethylene side chain. In the mesoporphyrin, the ethylene side chain is saturated. According to Robinson (above), the side chain can be an alkenyl. When it is alkenyl, the structure is similar to the protoporphyrin as taught by Drummond. According to Drummond, tin-protoporphyrins have proved to be innocuous in toxicology studies in animals. Even though Robinson teaches several metals one would prefer Tin since tin has been shown to be innocuous in toxicology tests.

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Long-term treatment of rats with tin-protoporphyrins resulted in decrease in bilirubin levels (page 90, middle paragraph; page 92, first full paragraph). From this it is seen that tin porphyrins, which are water soluble according to Robinson are also potent in controlling heme metabolism. Robinson need not necessarily teach this fact. Since

Bettelheim teaches that amino acids are zwitterionic and renders them water-soluble. It is logical to complex the porphyrins with them to increase the water solubility and to use them as substituents in the porphyrin of Robinson since Robinson teaches such porphyrins including amino acids as substituents that are water soluble. Based on Bettelheim's teaching the choice of amino acids is logical as a substituent since they increase water solubility and hence would increase absorption and bioavailability of the porphyrin. So, even though Robinson's teaching reads on millions of compounds, the secondary references, Drummond and Bettelheim suggest to one of skill in the art that tin mesoporphyrins complexed to amino acids is the best choice from the genus of Robinson. Hence there is a suggestion and motivation to combine.

Niedballa teaches all of the important steps as instantly claimed for making a porphyrin core which includes tin as the central metal ion and also states that secondary reactions like hydrogenation, esterification, and alkylations are all performed according to literature processes known to one of skill in the art (col. 11, lines 3-7; see office action mailed 4/14/2006). The method of Niedballa is a general one and can be applied to the porphyrin core. The yields are also high. Niedballa's goal may be different. Niedballa teaches that secondary processes are performed according to literature processes known to one of skill in the art. This means that it is well within the purview of one of skill in the art to use such processes for making mesoporphyrins as instantly claimed irrespective of whether they are water soluble or not. Since

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the porphyrin core containing tin and substitutions complexed to amino acids are water soluble (which is also suggested by Bettelheim) one of skill can use Niedballa's process to incorporate the necessary substitutions since it is art tested and some of the process steps are well known literature process steps that one can use to make any porphyrin.

***Conclusion***

Claims 2-5, 8-31 and 34-37 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

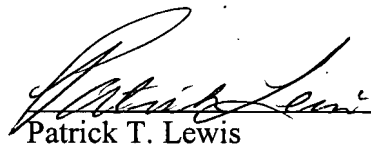
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



Patrick T. Lewis  
Primary Patent Examiner  
Art Unit 1623